

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE:)
) CA No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY AVERAGE)
WHOLESALE PRICE LITIGATION) Pages 1 - 51
)

MOTION HEARING (TWO)

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
February 8, 2011, 10:45 a.m.

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United States District Court
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1 A P P E A R A N C E S:

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P R O C E E D I N G S

THE CLERK: The case of In Re: Pharmaceutical Industry Average Wholesale Price Litigation, No. 01-12257, will now be heard before this Court. Will attorneys please identify themselves for the record.

MR. PAUL: Good morning, your Honor. Nicholas Paul for the California Department of Justice for California.

THE COURT: This is your second go-round, huh?

MR. KILMAN: Matthew Kilman for the Department of Justice, State of California.

MR. BREEN: Jim Breen for the relator, Ven-A-Care of the Florida Keys.

MR. MERKL: Neil Merkl for defendant Mylan.

MR. ANGLAND: Joseph Angland for defendant Sandoz, Inc.

MR. ESCOBAR: Bill Escobar for defendant Mylan.

THE COURT: Welcome back to a lot of you.

MR. SHAPIRO: Jonathan Shapiro for the relator.

MR. SLOTNICK: David Slotnick for the relator.

THE COURT: Okay. So we have our boxes and boxes of documents here. So let me ask you just as a starting, was this case filed here?

MR. PAUL: Your Honor, this case was originally filed in San Diego County Superior Court and wound up here through the MDL process and federal removal.

1 THE COURT: So eventually, if there's a trial, it goes
2 back to California. Is that correct?

3 MR. PAUL: That's correct, your Honor.

4 THE COURT: And the thought that I had is, I know
5 there was a motion to remand now which we'll get to, and there
6 may be certain crosscutting issues like what's a FUL, which
7 took us all about eight years to figure out; but there may be
8 some issues that are unique to California law, so does it make
9 sense for me to rule on a few things but not all things?

10 MR. PAUL: Well, speaking for California, your Honor,
11 I don't think so. I think the California False Claims Act has
12 a different statute of limitations perhaps than the Federal
13 False Claims Act or other state acts, but the essential
14 structure is similar. It's just different numbers. There's
15 not a line of case law in adjudicating it that's markedly
16 different from any other principles guiding statute of
17 limitations. The government knowledge issues --

18 THE COURT: So you representing California would
19 prefer for me to do the summary judgment motion here?

20 MR. PAUL: That's correct, your Honor.

21 THE COURT: Any trial, of course, would go back to
22 California, though.

23 MR. PAUL: Yes.

24 THE COURT: I think this should go up through the
25 Ninth Circuit and should have California jurors.

1 MR. PAUL: Yes, your Honor, I think that's the way we
2 see it.

3 THE COURT: Okay, all right. So you both have filed
4 cross-motions. Is anyone here from Dey?

5 MR. MERKL: Yes, your Honor, we also represent Dey.
6 Dey has settled.

7 THE COURT: Both parts?

8 MR. MERKL: Dey is completely out of this, the whole
9 thing. So to the extent you have a Dey motion, you can --

10 THE COURT: They're not getting their day in court?

11 (Laughter.)

12 MR. MERKL: Exactly. You can do whatever you do with
13 motions that don't have to be handled.

14 THE COURT: Okay. Okay, so cross-motions for summary
15 judgment and the motion to remand, do you want to start with
16 that somewhat threshold issue?

17 MR. ANGLAND: Yes, your Honor, I think all counsel are
18 agreed it makes sense to start there because depending upon
19 your ruling, it could moot the rest of the matters.

20 Obviously this Court has discretion regarding whether
21 to recommend remand at this point, and the question is whether
22 it makes sense to do so under these circumstances, and we think
23 that your Honor's ruling and the principles underlying your
24 Honor's ruling in the Montana and Nevada case apply here.

25 As your Honor pointed out in that ruling when she

1 remanded those cases while summary judgment motions were
2 pending, you had already issued a number of opinions
3 explicating your views that would provide guidance to
4 transferor courts, and that was better than a year ago, and
5 you've only added to the body of law since then, so there is
6 plenty of guidance out there. The question is, is what remains
7 in the summary judgment motions so much intertwined with the
8 other cases, as opposed to being unique to this case, that it
9 really does make sense to retain it? And I submit that it is
10 not.

11 Now, I'm certainly not going to suggest that there
12 isn't some overlap of issues. In any MDL you're going to have
13 some overlap from case to case.

14 THE COURT: Well, most of the issues are almost
15 identical. They just have different laws and different facts.

16 MR. MERKL: Well, okay, your Honor --

17 THE COURT: But the big issues are the same,
18 government knowledge, you know, that sort of thing.

19 MR. ANGLAND: Well, actually, the government knowledge
20 legal issue would be the same or at least pretty much the same
21 in all these cases, but the factual issue is just completely
22 different basically.

23 THE COURT: Right.

24 MR. ANGLAND: And that's what it really turns on.

25 Now, in their papers, the plaintiffs identified what

1 they said were four key issues that are so integrated between
2 the California case and the other cases that they would justify
3 keeping the case here. Now, of course, the same could have
4 been said about the Montana and Nevada case which had pretty
5 much the same issues.

6 The first issue was statute of limitations. Well, in
7 terms of the law, it is a different statute, and indeed, if you
8 get to the substantive summary judgment motions and you see the
9 summary judgment motion on statute of limitations, we cited a
10 federal case for a proposition, and we were admonished by
11 plaintiff that "Oh, that's federal law. It has no bearing
12 whatever. The California courts declined to follow
13 constructions of the federal statute of limitations." So
14 legally it's different to begin with.

15 But, more fundamentally, it's a discovery statute in
16 California, the statute of limitations. And so the issue then
17 is when California actually discovered enough to invoke, to
18 start the running of the statute of limitations. That is
19 inherently a state-specific activity. The evidence we're going
20 to point to there is a California version, but very different,
21 of the sort of evidence that was before your court in the
22 Massachusetts case where you focused upon what Massachusetts
23 did. Here, for example, we'll be pointing to documents from
24 California from the very beginning of the period where
25 California said, "Oh, there's a big spread here. The AWP is

1 200 some odd percent of the actual price, and that's a good
2 thing because that gives the profit that we want the pharmacies
3 to have." And actually, even with that bigger spread on a
4 generic drug -- there are generic drugs involved in this
5 case -- a high spread on a low-cost drug is cheaper for
6 California than a small spread on a brand-name expensive drug.

7 Now, I wish every state had that particular document.
8 They don't. Every state has its own documents. But the fight,
9 if you will, is going to be California --

10 THE COURT: That statement wasn't made till late in
11 the game, right?

12 MR. ANGLAND: No, it was 1988. And it wasn't a
13 casual --

14 THE COURT: Oh, it was very early in the game.

15 MR. ANGLAND: It was actually two years before the
16 beginning of the relevant period. And, your Honor, it was not
17 a casual document. What happened was, there was a proposed
18 change in the reimbursement system, and there were public
19 objections, and the Department of Health Services had to file a
20 formal response to the objections. And this was in their
21 formal response to the complaint that reimbursement levels
22 would be too low, and they actually point to more than a
23 200 percent ratio between the two and say, "This is a good
24 thing, and we'll save money."

25 Now, that's something that I wish I could use against

1 every state, but I can't. And that's one document. There are
2 hundreds of others. And I suppose, if you went to different
3 states, you'd find other documents that we think are good that
4 we'd like to rely upon, but the point is, they're different.
5 There is a little bit of overlap, I will concede that. The
6 little bit of overlap is the federal government issuing reports
7 that went to all the states saying, for generic drugs, the
8 discounts are 50, 60 percent, which leads to ratios of over
9 200 percent if you do the math. You can never get more than
10 100 percent discount, but you can have in theory an infinite
11 spread. It's taking the reciprocal basically. But we have
12 there a --

13 THE COURT: All right, so statute of limitations.
14 What's the second issue?

15 MR. ANGLAND: The second is just the government
16 knowledge defense, and I can save time because that overlaps
17 with what I just said. I also wouldn't characterize it as a
18 government knowledge defense as much as government knowledge
19 vitiating some of the elements of the various claims, but the
20 point is, you have to look at California, and what's true about
21 somebody else is not necessarily true of California.

22 The third is with respect to FULs, and here, the way
23 the issue has evolved, we have only a state-specific issue
24 left. In their papers, the state explicitly disavows one
25 theory of FULs. That was the one that was involved in the

1 New York case where the complaint was that the AWP's, the
2 published prices of the defendant companies, had caused the
3 wrong FULs to be set.

4 California here says, "No, that's not our claim.
5 We're making a different claim." Actually, it's a claim that
6 your Honor mentioned as a possibility in a footnote in one of
7 her prior opinions, which was adopted by the parties here, and
8 that is, even if the FUL was not adversely affected, we have a
9 "lesser of" statute in California. So if true AWP's, as they
10 would characterize them, had been filed, some of them would
11 have been lower than the FULs, and we would have paid less.
12 Well, that's a factual California-specific issue. There's no
13 great theoretical crosscutting issue there. Our position is
14 that California would not have on a systematic --

15 THE COURT: But don't they win on that issue as a
16 matter of law? I mean, if --

17 MR. ANGLAND: Well, as a matter of logic, I do not
18 dispute the proposition that if California said, "We're going
19 to charge the lower of the AWP or the FUL," and if they had
20 kept that position in place even with much lower AWP's, which is
21 a fact question, then I agree with their interpretation of the
22 statute. I don't have any quarrel with that. The quarrel
23 therefore is about a fact issue, which is, what would the AWP's
24 have been? And their expert actually disclaims having computed
25 what AWP should have been, so there's a fact issue there,

1 and --

2 THE COURT: Well, we all know it would have been lower
3 than the FUL.

4 MR. ANGLAND: Absolutely, your Honor, absolutely.

5 THE COURT: It has to be.

6 MR. ANGLAND: Well, we know it would have been lower
7 than it had been. We don't know that it would have been lower
8 than FULs.

9 THE COURT: Yes, we do, don't we?

10 MR. ANGLAND: Not necessarily, your Honor.

11 THE COURT: I can't think of a scenario where it
12 wouldn't.

13 MR. ANGLAND: Well, in fact there are lots of
14 scenarios. I mean, if you have a situation where there are two
15 different generics --

16 THE COURT: So tell me what a FUL is again.

17 MR. ANGLAND: Okay, a FUL is a Federal Upper Limit,
18 which is computed normally at 150 percent of the lowest
19 published price.

20 THE COURT: Right.

21 MR. ANGLAND: A given company may be less efficient
22 and may have a higher published price than somebody else, and
23 indeed the evidence in the New York case suggests that that was
24 often the case, that there was really one low price that might
25 generate the FUL, but that other people's real marketplace

1 prices might have been substantially higher.

2 THE COURT: But that they would ever be higher than
3 the AWP?

4 MR. ANGLAND: No, your Honor, if I may, I am not
5 saying that the real prices would have been higher than the AWP
6 that was published. That is not my position.

7 THE COURT: Oh, oh, oh, all right.

8 MR. ANGLAND: It might be easier with numbers. Let's
9 say the AWP was 100 and the FUL was 30. Well, it might be that
10 the true AWP, as plaintiffs would define it, would have been
11 35, would have been higher than the FUL, so it would have made
12 no difference. Now, they will say, "Ah, but maybe the AWP
13 would have been lower than the FUL, it would have been 25."
14 Well, maybe, but what we have here is a fact-specific issue, is
15 a very much fact-intensive issue. We also have the over- --

16 THE COURT: Maybe. I don't know. Could you find some
17 outlier where that was true? Maybe. But you could say,
18 typically speaking, that was highly unlikely.

19 MR. ANGLAND: I don't think so, your Honor. I have
20 seen nothing in the --

21 THE COURT: Well, anyway, FUL strikes me as a
22 crosscutting issue for us.

23 MR. ANGLAND: And if I may, your Honor --

24 THE COURT: I think we've ruled on it.

25 MR. ANGLAND: Well, your Honor, there are two

1 different theories regarding FUL. Your Honor has ruled on one,
2 and on that you've already provided the guidance you want to
3 provide. Your Honor has also written in a footnote, not in a
4 ruling, something which expounded this theory of, if you will,
5 FUL liability. The first theory was: The defendants distorted
6 the creation of FULs. That's what you ruled on in New York.
7 That's not the issue that's being pressed here. Here the issue
8 is, even assuming that the FULs were not distorted by
9 defendants, California would have charged less than the FUL
10 amount. They would have charged the AWP amount --

11 THE COURT: The true AWP.

12 MR. ANGLAND: -- because AWP is lower, the true AWP
13 amount where the AWP was lower than the FUL. And that is a
14 fact question. There's no great cosmic issue to be determined
15 there. As you said, your Honor, that's what the statute says.
16 The only question is, would California have, in response to
17 that sort of lower AWP, said, "No, that's not giving enough
18 profits." The fight is a factual one. There's no conceptual
19 issue to be dealt with. The conceptual issue you dealt with in
20 the New York case. Now, I respectfully disagree with the
21 dealing with it, but you dealt with it, and there's nothing
22 left to be dealt with there.

23 The fourth and final sort of crosscutting issue was
24 that it would facilitate settlement to keep all these cases in
25 one place. Well, that doesn't really work, if you will. We've

1 just been going through some settlement discussions with and
2 without a mediator, and the parties have been very free to pull
3 in cases that are not before this Court with cases that are
4 before this Court to talk about various permutations of what
5 can and can't be settled. No one has ever felt bound by the
6 jurisdiction of the District of Massachusetts in terms of
7 deciding how to package a settlement. So whether or not that
8 was perceived as an issue a year ago --

9 THE COURT: I'll go into settlement when we go off the
10 record. That's usually my --

11 MR. ANGLAND: Right, and I have no intention of
12 referring to the substance at this point. My only point is
13 that settlement is not a reason to either remand or to not
14 remand because the parties here are sophisticated enough; we
15 can talk about any combination of cases in settlement that we
16 want to take.

17 So at the end, your Honor, this situation is really
18 identical to that in Montana and Nevada. There is some overlap
19 of issues, but they're basically local issues. This is
20 California law and California facts. The background on how AWP
21 works and how FULs works, that's been dealt with. You said
22 over a year ago that you had provided ample guidance, and you
23 had. And so in the end what we have are fact issues, and
24 they're fact issues unique to California, and some legal issues
25 unique to California, and for those, there's really no need to

1 have multi-districting. And, frankly, as a trial lawyer, your
2 Honor, I'd like to get this sooner rather than later in front
3 of the judge who's actually going to be presiding over the
4 trial, personal preference, but in terms of the actual criteria
5 in terms of when --

6 THE COURT: Well, I'm sympathetic to it, and I'm also
7 swamped, and I spent an entire weekend reading everything,
8 which is huge, so there's an overwhelming preference to have
9 somebody else write it, since I've written so many of these.
10 On the other hand, some of these issues like FUL are very
11 complicated, and at least one of the issues I think I'll
12 handle, and on the others, I don't know whether government --
13 well, let me ask you this: Government knowledge, all that,
14 statute of limitations, why doesn't it just make sense to have
15 the judge out there deal with it? She or he could do it just
16 as well as I could.

17 MR. PAUL: Your Honor, first, as to the -- well, just
18 to back up, I think this is an average wholesale price
19 litigation MDL, and we are the first pure state average
20 wholesale price case before you. I mean, we are a poster child
21 for MDL coordination, I think.

22 THE COURT: I've had, although it was not part of the
23 MDL, I just had a monthlong trial with Mylan, but that was a
24 WAC case.

25 MR. PAUL: Yes, your Honor, and I understand that.

1 THE COURT: But many of the issues, many, many of them
2 overlapped, the "lesser of" methodologies, the "what's a claim"
3 and --

4 MR. PAUL: Yes, your Honor, I understand that, but
5 this is a pure average wholesale price case, I think, as you've
6 seen from the briefing. And, incidentally, we try not to
7 deluge you. We've got three blue binders of briefing. This
8 is what we responded to. Defendants are in red, for what
9 that's worth, your Honor.

10 THE COURT: I know, I recognize all those binders.

11 MR. PAUL: The statute of limitations, your Honor, you
12 have said in several cases that statute of limitations analysis
13 is a drug-by-drug inquiry, and inevitably it's intertwined with
14 government knowledge issues. It's messy, and the government
15 knowledge issue I think is one of the most critical areas where
16 this Court's coordination of a focused, consistent approach is
17 necessary, rather than sending these summary judgment issues
18 that are teed up in front of you back to a District Court judge
19 in California who knows nothing about this case. This case was
20 in the hands of a District Court judge in the Central District
21 of California for no more than three months, and it was never
22 looked at. The entire issue was whether or not the federal
23 removal would be successfully contested by the state and then
24 the administrative aspects of sending it to this MDL. So
25 there's no familiarity on the part of any district judge with

1 this case back there.

2 Ultimately this Court may decide once again in this
3 case -- we don't think you need to -- but it may well decide
4 that, again, the statute of limitations issue is a drug-by-drug
5 inquiry, but that inevitably takes us to the heart of the other
6 issues in this case. Counsel described a 1998 document. I
7 confess I was unable to pick up on the identity of the document
8 as he spoke, and I'm sure that will be clarified, but this is
9 just one of -- the defendants' argument in this regard is that
10 the California program, essentially every time it attempted to
11 undertake any sort of an analysis or reach out to various
12 stakeholders and respond to them and justify their adjustments,
13 that that constitutes government knowledge and California
14 loses. It's kind of a simplistic argument, I think. There is
15 no evidence in the record -- and this anticipates the main
16 motions -- but there is no evidence that California ever
17 understood the extent of the spreads in the defendants' drugs,
18 or, much less, that it --

19 THE COURT: Well, they did when that study came out in
20 2002, right?

21 MR. PAUL: Well, the Myers & Stauffer study undertook
22 an analysis of pharmacy acquisition costs.

23 THE COURT: Well, isn't that what we're talking about?

24 MR. PAUL: Well, it is, your Honor, but it was not a
25 study of all of the defendants' drugs.

1 THE COURT: Most of them, though, right?

2 MR. PAUL: I'm not sure that "most of them" is
3 accurate.

4 THE COURT: Well, maybe I am jumping into the merits.
5 So the first time you have a drug-by-drug understanding of the
6 extent of the spreads was in 2002.

7 MR. PAUL: That's right, your Honor.

8 THE COURT: So then the issue becomes, at that
9 point --

10 MR. PAUL: How long do you give California?

11 THE COURT: -- how long do you give California to fix
12 it?

13 MR. PAUL: We have cut our case off in 2004, your
14 Honor.

15 THE COURT: I noticed that.

16 MR. PAUL: So I think that's an important point.

17 THE COURT: Because at that point you'd have to agree
18 they knew.

19 MR. PAUL: Well, they knew as to the drugs that were
20 identified in the Myers & Stauffer --

21 THE COURT: But also on fair inquiry notice on
22 anything else. I mean, at that point the cat was out of the
23 bag, if it wasn't in --

24 MR. PAUL: Yes, your Honor, and they took that study,
25 and then they changed AWP-based discount from minus 10 to

1 minus 17 in 2004.

2 THE COURT: Right.

3 MR. PAUL: And that was based, as the record
4 indicates, primarily on the fact of that study. But I think
5 that it's fair to give --

6 THE COURT: You know, there's another McKesson case in
7 front of me now where they claim that that's because of the
8 extent of the spread, the increase in the 5 percent average
9 wholesale price by McKesson. So both people are attributing
10 the 17 percent to a different cause. I'm just -- I happen to
11 have them both right simultaneously in front of me, but --

12 MR. PAUL: I'm not sure if that's good for you or bad,
13 your Honor.

14 THE COURT: I don't know either. It's bad when you're
15 seeing two different theories, knowing more about California
16 reimbursement policy than most other states. So let's just --

17 MR. PAUL: The Montana and Nevada remand, your Honor,
18 I think that was four years ago, and there have been a number
19 of opinions this Court has issued since then, and a number of
20 them are crucial to the landscape of this case. And I don't
21 think that just because they were remanded -- I don't think
22 that was well briefed back then. I think it was sort of ad hoc
23 the way it came up, and there wasn't a great deal of opposition
24 from the plaintiffs.

25 THE COURT: And I believe that all of the claims arose

1 under the --

2 MR. PAUL: State law claims.

3 THE COURT: -- state law, not that they don't here,
4 but they were very unique to Montana and Nevada Medicaid law,
5 but, you know, some of them are unique to California Medicaid
6 law.

7 MR. PAUL: That's true, your Honor. There is one
8 other factor here. This is a whistleblower case involving
9 Ven-A-Care, and Ven-A-Care is before you in a number of other
10 cases, as I'm sure you're aware.

11 THE COURT: Right. There's a big article about
12 Ven-A-Care in PharmaGossip. Did you see it?

13 MR. BREEN: I heard about a couple of those, Judge.

14 MR. PAUL: Describing Mr. Breen as a pit bull, your
15 Honor?

16 THE COURT: I think that was the one.

17 (Laughter.)

18 MR. PAUL: We do not explicitly disavow the New York
19 counties' FUL theory at all, your Honor. New York is mandated
20 to pay on a FUL, as you're well aware. Therefore, the way to
21 establish falsity was to undertake the analysis, which the
22 plaintiffs did; and that established, on top of the AWP injury,
23 that the defendants have caused, at least as to those nine
24 drugs, the entire FUL system to be contaminated with false --

25 THE COURT: Well, what do you say about your brother's

1 suggestion, that even you said that many drugs of the AWP would
2 have been lower than the FUL, you can't do that on a wholesale
3 basis, that there may be a few outliers there where that wasn't
4 the case?

5 MR. PAUL: Well, your Honor --

6 THE COURT: How do I address that?

7 MR. PAUL: I think one way to look at it is that
8 California pays on a "lowest of" system, as the Court is well
9 aware. And that means, if the usual and customary is lowest,
10 that's how it gets paid, if the FUL is lowest, et cetera. Our
11 expert, using the same claims data that was provided the
12 defendants with our initial disclosures, identified 312,000
13 instances in which California paid at one of their AWP's which
14 was lower than the FUL. So the California system works at its
15 "lowest of" method, and for the defendants to contend that we
16 never could have run a program paying at less than the FUL is
17 belied by that simple fact.

18 THE COURT: I think what his point was, that
19 occasionally the AWP may have been higher than the FUL.

20 MR. PAUL: Most of the time AWP's were higher than
21 FUL's.

22 THE COURT: No, I'm sorry, I said that incorrectly.
23 The true AWP.

24 MR. PAUL: Well, the true AWP that was calculated by
25 our expert is --

1 THE COURT: Is it always lower?

2 MR. PAUL: I believe it's almost always lower, your
3 Honor, yes, and one way to --

4 THE COURT: So is that the in the record? I didn't go
5 through it. So your expert went out and actually calculated
6 the true AWP --

7 MR. PAUL: Yes, your Honor.

8 THE COURT: -- for every single one of the challenged
9 drugs in the NDCs?

10 MR. PAUL: Yes, your Honor, and that's set forth in
11 Exhibit 4 to his report. I'm sorry. Exhibit 5 is a statement
12 of the damages. Exhibit 4 is a statement of the spreads.

13 THE COURT: And he proves up that every single true
14 AWP for the challenged drugs was below the FUL?

15 MR. PAUL: No, your Honor, no.

16 THE COURT: The true ones, the true ones.

17 MR. PAUL: I cannot stand here and tell you that every
18 single true AWP was at all times lower than the FUL.

19 THE COURT: So you would exclude those from your
20 damages then?

21 MR. PAUL: Your Honor, we claim damages anytime that
22 his calculated AWP for a particular claim was higher than the
23 price at which the claim was actually paid, regardless of the
24 basis on which it was paid. I may be saying the same thing as
25 your Honor. I'm not sure.

1 THE COURT: Given his example, if the false AWP, the
2 phony one, was at 100 and the true AWP was 35, his true AWP --

3 MR. PAUL: And the FUL was 30.

4 THE COURT: -- and the FUL was 30, I'm assuming you
5 would have paid at the FUL and they wouldn't be liable.

6 MR. PAUL: That claim is not in the case, your Honor,
7 that's correct.

8 THE COURT: Okay.

9 MR. MERKL: Your Honor, the record, we disagree with
10 that characterization of what their expert purports to do. My
11 understanding of Professor Leitzinger's work is, he explicitly
12 disclaims that he is calculating what should have been reported
13 as an AWP. What he says he is doing is, he is looking at our
14 data, crunching a number that is a fully down-to-the-bone
15 absolute discounted number, and then he just grosses it up by
16 15 to 20 percent based on some assumptions he was asked to
17 make, I believe by counsel. I don't think he's saying this is
18 an AWP that should have been reported. Also --

19 THE COURT: Well, what was he saying it was then?

20 MR. MERKL: It's part of his damage analysis.

21 THE COURT: No, no, no, excuse me. But let's just say
22 that's his best estimate of what the AWP was likely to be, that
23 sounds good enough.

24 MR. MERKL: Well, I think he is not saying as an
25 expert, "And this is what I think AWP should have been." He's

1 not making that determination because if you look at what the
2 California --

3 THE COURT: Well, let's say he is going to say. Let's
4 say he -- let me just say this, that, you know, there are lots
5 of different terms for these things, the true one being the ASP
6 or the AMP. I mean, people have come up with different ways of
7 thinking about it, but let's just say, "This is my best
8 estimate based on the data I have of what the true AWP was."
9 Now, you might want to refute that and say, "No, the true AWP
10 was different," but why isn't that a fair expert opinion on his
11 part?

12 MR. MERKL: I guess I'm not saying it's not a fair
13 expert opinion on his part if he had actually opined, "This is
14 what AWP should have been." He's not saying that.

15 THE COURT: Excuse me. Do you think he is?

16 MR. PAUL: Your Honor, our expert did not want to --
17 he calculated an AWP, and he explained it should have been a
18 "but for" AWP, and he explained it's utterly transparent as to
19 how he got there. He calculated a wholesale net cost using the
20 defendants' own data, and he built in numerous corrections to
21 the benefit of the defendants based on the fact that California
22 has certain economic inefficiencies, it --

23 THE COURT: So he scaled it up for the normal margin,
24 the profit margin from the --

25 MR. PAUL: He started off, he added 2.7 to 5.4 percent

1 which is the --

2 THE COURT: The wholesale.

3 MR. PAUL: The wholesale, correct, your Honor. And
4 that was the "but for" AWP that he calculated. He said, "I
5 cannot opine that this is the AWP that the defendants should
6 have reported because I think that is a matter of law."

7 THE COURT: Excuse me. Let me just say this: Why
8 isn't that fair? He takes essentially the WAC, whatever the
9 acquisition cost over the wholesaler -- sometimes it's called
10 the wholesale -- what's it called, net acquisition cost or
11 wholesale acquisition cost? -- and he nets up the profit.

12 MR. MERKL: I think that's what he's doing, and I
13 think what he's computing is kind of an alternate version of
14 AMP.

15 THE COURT: Yes, but that's what people have been
16 using as a proxy all along in this litigation.

17 MR. MERKL: And one of the problems with using an AMP
18 as an AWP is that an AMP incorporates down the line discounts
19 that aren't known and could not be known.

20 THE COURT: That's a different issue.

21 MR. MERKL: I think one of the reasons, though, this
22 is so confusing now, your Honor, is, they have not moved for
23 summary judgment on the FUL theory. This really isn't in the
24 papers. What happened is, we filed a motion --

25 THE COURT: Well, maybe not, but I do think the FUL

1 issue is in those boxes of documents you gave me. So let me
2 just ask you, so it's not --

3 MR. MERKL: This particular issue that we're arguing
4 about now really is not. We argued that based on FUL, their
5 claim should be reduced because they had not proved up --
6 there's a similar argument that later we lost on, to be blunt,
7 in New York, that because of the way FULs are set --

8 THE COURT: Right, that's the one I remember, and
9 that's the one I resolved, and that's the one I should tell the
10 California court about.

11 MR. MERKL: And that's really the only FUL issue here.
12 The one we're talking about now about summary judgment on FUL
13 hasn't been made and we haven't addressed it.

14 THE COURT: Well, your brother just raised it, so, I
15 mean --

16 MR. MERKL: I know he raised it, but I thought we were
17 just getting into why isn't this --

18 THE COURT: I mean, this might be one that's
19 crosscutting and unique to me. That's all I'm saying.

20 MR. ANGLAND: Your Honor, if I could add briefly on
21 that, I mentioned FUL because it's one of the four issues that
22 they flagged as cutting across issues.

23 THE COURT: It is.

24 MR. ANGLAND: The way FUL arises here is, when we move
25 for summary judgment, we make a number of arguments about why

1 they can't establish causation. One of them is FUL. So
2 basically, if we were to lose the FUL issue, what that would do
3 is remove one of six or seven grounds on which we are moving
4 for summary judgment. What we don't have here is the record
5 that was established in New York. In New York the claim was,
6 FULs got distorted because inflated prices were published.
7 It's basically what your Honor concluded. In our opening
8 papers, we challenged that and pointed out there was no record
9 evidence here. And these papers were written before your
10 New York opinion, by the way, your Honor, and so there's no
11 record evidence to establish it.

12 Here, California did not respond the way New York did.
13 New York responded by trying to show how FULs were distorted by
14 published prices by the defendants. California submits
15 nothing. There's nothing in this record on that. It's
16 completely silent. Instead they say, "No, defendants, you
17 misunderstand our theory of FUL. Our theory isn't that the
18 wrong FULs get set. Our theory is, there's still causation
19 because of the 'lesser of' standard," the analysis your Honor
20 just properly explained. So all we have here now is really an
21 argument of what the "lesser of" price would have been in
22 California.

23 THE COURT: Yes, but I'm not going to -- all right, at
24 least I understand the issue. That is one that is very
25 difficult, it took us years to understand, and might be of some

1 guidance to another court, as opposed to government knowledge,
2 which it's an evolving concept but it's just basically
3 fact-based.

4 MR. PAUL: It is, your Honor, but I think that it
5 necessarily contemplates how Medicaid runs, the concept of EAC
6 and how these large, cumbersome, complex agencies work.
7 California's Medicaid program supports seven million people.
8 That's more than the population of thirty-eight states. It's a
9 huge, sprawling bureaucracy.

10 THE COURT: It's huge.

11 MR. PAUL: You cannot turn it on a dime, and you
12 cannot impugn government knowledge to the agency based on an
13 honest, forthright discussion with stakeholders who are
14 complaining about a proposed reimbursement change.

15 THE COURT: Those are the statements that happened
16 very recently, right? There were a few statements that were
17 quoted which were after that report.

18 MR. PAUL: After the Myers & Stauffer 2002 report.

19 THE COURT: Yes.

20 MR. PAUL: Yes, your Honor.

21 I did want to reserve a few minutes for Mr. Breen on
22 the issue of remand as well.

23 THE COURT: Yes, go ahead.

24 MR. BREEN: Just briefly, your Honor, as you're aware,
25 Ven-A-Care has before your Honor Boston-filed federal cases

1 under the United States False Claims Act with respect to
2 Sandoz, Mr. Angland's client, and also a small piece of it's
3 left with respect to Mylan -- we settled the rest of it -- as
4 it relates to the --

5 THE COURT: I didn't know there was anything left in
6 that. What's left in Mylan?

7 MR. BREEN: Just the California, the United States'
8 interest in the California claims, so that is left with respect
9 to Mylan. And so --

10 THE COURT: So when I send this back, which I may well
11 eventually, does that go with it?

12 MR. BREEN: No.

13 THE COURT: Why?

14 MR. BREEN: Because it was a case that was initiated
15 here in Boston. We filed it in this district. It is a Boston
16 federal false claims case.

17 THE COURT: Yes, but it could be under 1404 if it's
18 all California.

19 MR. BREEN: Theoretically it could or --

20 THE COURT: The general transfer statute.

21 MR. BREEN: I mean, the other way is, we could go back
22 to California and transfer that here because most of the cases
23 are here, so it's kind of a -- but you're right, that's the
24 transfer statute. But the point I wanted to make, though, your
25 Honor --

1 THE COURT: Whatever it is, it should be in one forum.

2 MR. BREEN: I think we've agreed to that, haven't we?

3 MR. MERKL: We don't really have a disagreement on, I
4 think, how we're going to work that at all. We both agree we
5 have to work it out, we both agree it should be one case, and I
6 think we just have to hash out how we're going to do that.

7 MR. BREEN: We may have a difference of opinion on how
8 we get it to one case, but I think we're in agreement that it
9 ought to be one case in terms of the relator and Mylan.

10 THE COURT: All right.

11 MR. MERKL: Because the overlap is the same matter.

12 MR. BREEN: But the point I want to make, Judge, is, I
13 mean, this is the AWP MDL, and we've been here for a long time,
14 and the California case has been here for a long time. The
15 litigants and the lawyers have worked real hard to get as many
16 of these things resolved, including my brothers here today, to
17 get as much of this stuff resolved as we can nationally, but --

18 THE COURT: This is not resolvable.

19 MR. BREEN: It hasn't been yet, and we can talk
20 about -- as your Honor indicated, that might be something we'd
21 want to talk about. But my point is, this is really the first
22 time the MDL court has been asked to rule on where AWP, a
23 straight AWP reimbursement system falls under a False Claims
24 Act; not common law fraud where there's reasonable reliance;
25 not between two arm's length business people where there's all

1 that. I'm talking about a straight-up False Claims Act that's
2 on all fours as far as the unlawful acts or the acts go with
3 the United States federal False Claims Act. And so the risk of
4 conflicting decisions on this core point is exactly why we have
5 an MDL. So we'd respectfully submit, your Honor, that all
6 these issues on liability that we've teed up --

7 THE COURT: No, I understand that and appreciate that
8 point, and it may be that I'd be helpful in ruling on some of
9 the issues, but when I get to government knowledge -- I mean,
10 maybe we're just morphing into the merits, as I read
11 everybody's briefs -- you're both cross-moving for summary
12 judgment on government knowledge. It may be more complicated
13 than that. For certain periods of time, no way, there's just
14 not enough; for certain periods of time, you know flat out.
15 But then I don't know that I could rule as a matter of law how
16 quickly you have to turn the Queen Elizabeth; I mean, you know,
17 once they know, which they do with the Myers & Stauffer, you
18 know, how quickly you have to do something. That may be a jury
19 question.

20 MR. BREEN: But I think, your Honor, it's a core
21 issue. A gut issue here, though, is, under the Federal False
22 Claims Act and the California False Claims Act is, when the
23 pharmaceutical manufacturers make misstatements of price, if
24 the law is going to be or the Court determination is going to
25 be that California or the United States has to change their

1 reimbursement system because of misstatements of price, that is
2 a critical legal determination that is going to be far-reaching
3 in these cases and all kinds of cases. And talking about
4 government knowledge for statute of limitations is one thing,
5 but right now we're talking about government knowledge in that
6 whether or not there's acquiescence to a particular defendant's
7 conduct or whatever. What you're saying here, your Honor, I
8 believe is: At some point maybe we'll find that the United
9 States has to change their reimbursement system and California
10 has got to change theirs because drug companies aren't telling
11 the truth. And that is a critical gut, core issue, that if
12 that's going to be determined one way or the other -- and
13 obviously we have some strong opinions about it -- then that
14 needs to be determined in the MDL, not multiple decisions out
15 there for everybody to decide.

16 On statute of limitations, though, that's a different
17 issue, in my opinion, in relator's opinion; and whether or not
18 a particular government civil prosecutor office was placed on
19 sufficient notice to start the running of the statute, I think
20 that's a totally different question from this huge issue of
21 government knowledge --

22 THE COURT: Well, that's a very good point, Mr. Breen,
23 which is essentially you're saying, all right, there are just
24 certain policy issues that the MDL court should decide, and so
25 maybe I'd carve off statute of limitations, which would be

1 maybe nothing so special in terms of who knew what when and
2 what triggered the duty, as opposed to the basic policy issues
3 that are crosscutting.

4 MR. BREEN: Exactly.

5 THE COURT: I hear that, and I'm tempted actually
6 because I have a vested stake here, but the truth is -- and
7 here's what the big problem is -- and poor Mr. Sobol was here
8 yesterday with the McKesson case, and I just finished up the
9 AstraZeneca case, and I have a huge Neurontin case, and I just
10 became Chairman of the United States Sentencing Commission --
11 you may not know that -- it could take a long time to get out
12 this opinion. And the concern I have here -- I know what the
13 situation is in California -- you can't help but read the
14 newspaper, even here in Boston -- I'm worried because one piece
15 of this has got to be the congestion in this court with the
16 huge numbers of drug cases that I'm dealing with. So I'm
17 trying to figure out some manageable piece of this that I could
18 help a court out there with without the massive opinion that
19 would necessarily flow should I go through every piece of this
20 record on every company and every drug on statute of
21 limitations. So I'm looking for a middle ground, if you will,
22 and this is a very helpful discussion, really.

23 MR. BREEN: Absolutely.

24 MR. ANGLAND: Your Honor, if I can just respond to
25 Mr. Breen's point specifically. On government knowledge as it

1 relates to liability as opposed to statute of limitations,
2 there are really two elements: What should the law be, and
3 then what are the facts? Your Honor has written I think three
4 opinions that explain that just having some government
5 knowledge is not enough, and you explain how the cases say
6 either that there must be government approval or there must be
7 government knowledge of really all the detailed facts on
8 liability. Now, putting aside any objections we might have to
9 that law, your Honor has said that, it's there. What's left
10 are the facts.

11 THE COURT: The cases aren't specific. I have written
12 on it a number of times, and it's come up recently, but the
13 touchstone is, it's not mere knowledge, but neither does there
14 have to be a formal, as you would say, approval and a rule or a
15 vote, but it's got to be that it's an affirmative adoption of
16 it as a policy. And I'm saying it probably not so precisely.

17 MR. ANGLAND: I understand what you're saying, your
18 Honor, and I guess my point was going to be that that really
19 only can be assessed in light of the facts. It's one of those
20 things that I think your Honor would probably not start and
21 just describe, you know, sort of a civil law rule that the
22 following are exactly the criteria. You would look at what
23 happened in the state, and what happened in California is
24 different from what happened anywhere else. And so other
25 really than having the principles you've already articulated in

1 general about the role of government knowledge, what would be
2 left would be the application of those principles to the facts
3 of each case, and every case is different.

4 THE COURT: Well, let me ask you this: I mean, it did
5 strike me there are different time periods. For sure, you have
6 the strongest case by far and away, maybe even as a matter of
7 law, at some point after Myers & Stauffer; but, as he points
8 out, they stopped the case in 2004. Wouldn't it be a jury call
9 as to how quickly, once you know the facts, you have to change
10 things?

11 MR. ANGLAND: Well, if Myers & Stauffer were at the
12 beginning of the knowledge, then I think I would agree with
13 you, but, you know, we point to knowing that there were, you
14 know, 50, 60 percent spreads, which again -- I'm sorry -- that
15 there were discounts of 50 or 60 percent, which means sort of
16 200 percent ratios back in 1996. And the document I referred
17 to before was the 1988 document which says, no, this
18 200 percent ratio is a great thing. That's two years before
19 the case began.

20 Now, Mr. Merkl is going to actually argue the merits
21 of the government knowledge stuff, so I don't want to preempt
22 his thunder on it --

23 THE COURT: All right, maybe we should just -- that's
24 the key issue here, the government knowledge really. The
25 cross-motions, for sure, if I say there are questions of fact,

1 that goes back to a California court, and I'm likely to send
2 both of them back.

3 MR. MERKL: Your Honor, government knowledge, the
4 questions of fact that we raise in response to their motion for
5 summary judgment, we're missing a couple of them here. I mean,
6 they're presenting our government knowledge argument as though
7 it's a fait accompli we commit fraud; that we lied, we knew
8 what we were doing, we shouldn't do this, and the government
9 approved it, so it's okay, we should get a pass. That really
10 isn't the whole story.

11 Our argument, it's like the way you charged the jury
12 in the Massachusetts case. You have to break the California
13 False Claims Act claims down into its elements, and two of
14 those elements are materiality and scienter. And if you look
15 at the body of documents and legislative history and what went
16 on in California, that's how you have to evaluate materiality.
17 Here what we're arguing, it's not as though we're claiming we
18 admit we did something wrong, we should get a pass. What we're
19 saying is that California understood their system fundamentally
20 differently. In 1977, for instance, California defines AWP, or
21 maybe -- California issues a report --

22 THE COURT: Excuse me. You've been peddling this
23 theory all along that somehow they were going to give the
24 publishing companies a free pass on whatever they wanted to
25 print.

1 MR. MERKL: No, no, no, this is different.

2 THE COURT: All right, all right.

3 MR. MERKL: All I'm saying is, the California
4 Department of Finance had a report, said, "What is AWP? We
5 have to look at it. We're figuring out how we're setting these
6 price ceilings." And they define it. They say AWP, unlike the
7 list price, is a price set that's used to take discounts off,
8 which is what we've been saying, all right?

9 You move ahead to '86, '87, right? CMS changes the
10 rule. CMS decides, "We need to promote the use of generics.
11 We need to allow them to get a profit on these things."

12 California then has a document, '86, '88, where they
13 go through an example saying: Here is a drug. The AWP is, I
14 forget, \$100. The actual sale price is \$50, okay? But that's
15 good because that \$50 spread is going to incentivize the local
16 druggist to buy generics.

17 Our point is that you have to look at the California
18 system that way, that in part this is by design, that they knew
19 that AWP is a benchmark, not a true approximation of an
20 average. And I am not saying that that means it can be
21 anything we want it to. I understand that, and I'm not saying
22 that. I am saying that, really, the world of generics is an
23 entirely different world. It is not how this case started out.
24 When we started out with these cases, we're looking at
25 marketing the spread. Remember that? They're going into

1 doctors' offices. They're raising spreads \$100 so the doctor
2 can make \$400 instead of \$100.

3 THE COURT: Right, that's how we started.

4 MR. MERKL: That has nothing to do with the world of
5 generics. Generics is completely different. We're not selling
6 to doctors. These big spreads that you'll see from time to
7 time when you see an AWP of \$10 and we're only selling it for
8 \$1, we lose money on that spread. It's a true spread. We're
9 discounting. We're giving away our money. Our money is going
10 to the pharmacist on that discount, not the state money. The
11 state is still playing the same flat amount. When you look at
12 the --

13 THE COURT: You know what, stay on track there because
14 I don't think I have anything in the record that you were
15 losing money. I don't totally believe it, but --

16 MR. MERKL: I'm not saying we're losing. I'm saying
17 that we're not making money on the spread. It's not a
18 situation where, like, you can go in, right --

19 THE COURT: No, but excuse me. Let me just say, I
20 understand the core argument here has always been -- it was
21 true in Massachusetts and is true here -- that basically the
22 government turned a blind eye to known spreads because they
23 wanted to either, A, incentivize the pharmacists to use the
24 generics, or, B, they weren't paying a high enough dispensing
25 fee and couldn't get that through the legislature, and this was

1 sort of a cross-subsidy.

2 MR. MERKL: Yes, right.

3 THE COURT: Those have been the two big arguments that
4 you raise, that there was an affirmative conscious policy
5 decision on those two grounds, right?

6 MR. MERKL: Yes.

7 THE COURT: And so they then disagree with that, and
8 the question is -- I spent a month in Mylan, actually
9 Schering-Plough, Warrick, what was left, basically trying that
10 case, and so I don't see how that doesn't get tried.

11 MR. MERKL: Well, I agree with you. That's my point.

12 THE COURT: I thought you both were cross-moving for
13 summary judgment on government knowledge.

14 MR. MERKL: Our only summary judgment motion where we
15 want judgment is that 2002 post-Myers & Stauffer's point and on
16 the statute of limitations point --

17 THE COURT: But you can't win post-2002 because
18 governments are governments. Have you ever worked for the
19 government?

20 MR. MERKL: No.

21 THE COURT: Yeah, well, let me tell you, let me tell
22 you. Well, let's even start with what the pharmacies did to
23 me, never mind what they do to the legislatures. I mean,
24 they're very vocal and a strong force, and it takes a while to
25 craft a compromise, or at least sort of get past the politics,

1 right?

2 MR. MERKL: Yes.

3 THE COURT: So I think you can't say, bingo, they had
4 to turn on a dime the minute the Myers & Stauffer report came
5 out.

6 MR. MERKL: That's not our whole argument. The reason
7 why it should end at Myers & Stauffer in 2002, at least as a
8 matter of law, is because of the element of materiality unique
9 to a False Claims Act claim. Once they know that you have
10 spreads of 80 percent, 60 percent, right --

11 THE COURT: 1,000 percent, 5,000 percent.

12 MR. MERKL: All right, once they know all that and
13 they sit down -- and they do take a year and a half, they do
14 meet with the lobbyists, they do do all this --

15 THE COURT: Right, of course.

16 MR. MERKL: -- they don't knock it down that. They
17 just knock it down 5 points. That tells you --

18 THE COURT: That can't be a matter of law.

19 MR. MERKL: Well, but our argument is --

20 THE COURT: That's a good argument for a jury.

21 MR. MERKL: But that tells you that these spreads are
22 not material in the sense they argue they are.

23 THE COURT: Not as a matter of law. So that's where
24 I'm struggling with your position, and it may be that early
25 on -- I have to go back and reread this 1988 memo. Have you

1 figured that one out yet?

2 MR. PAUL: Your Honor, I think the short answer to
3 that 1988 memo is, it's like other documents that the
4 defendants have pointed to: It shows some general awareness
5 that there is an AWP inflation problem. But this is a program
6 that spends \$6 billion a year on drugs, just drugs. It's a
7 \$45-billion-a-year program. Eighty percent of that expenditure
8 is for branded drugs where this AWP fraud, to be blunt, is not
9 in evidence, not the way it is with generic drugs. And there
10 is not a single document that the defendants have pointed to in
11 their briefing -- and I know that Sandoz has an AMP argument,
12 and I'm not trying to bulldoze over it, but setting that
13 aside -- there's not a single document that the defendants have
14 pointed to that identifies any instance in which the program
15 knew that their drugs were inflated to the extent that they are
16 until the 2002 Myers & Stauffer report.

17 So if it's enough to defeat a False Claims Act if the
18 program is out there stumbling around trying to identify
19 without any constructive input from the defendants, who of
20 course never respond to any of these OIG reports or Myers &
21 Stauffer or any other report saying, "California Medicaid, we'd
22 like to come clean with you. Those spreads, we agree, those
23 are way too high," there's none of that, of course. So they're
24 operating pretty much in an information vacuum with regard to
25 their ability to identify any attribute of the true, accurate

1 average wholesale prices, giving that term a fair common-sense
2 meaning as this Court has done over and over again.

3 THE COURT: All right, thank you. I've read this. I
4 want to make sure we have a chance to do all the individual --
5 are you looking for summary judgment on the FUL point or --

6 MR. PAUL: Your Honor, we've moved for summary
7 judgment on two counts under the California False Claims Act:
8 The defendants caused false claims to be presented, and that
9 they caused false statements to be made in the paying of
10 claims. So it's that simple. One of their grounds on which
11 they have moved for summary judgment is that California has no
12 claim for damages for any claim paid at a FUL, and we of course
13 oppose that and --

14 THE COURT: All right, thank you. So can we just --
15 the one piece I feel that I -- only individual motions that
16 have unique issues.

17 MR. MERKL: Mylan and Sandoz each made a motion on
18 statute of limitations, which I think we've already covered.
19 When this motion was originally filed, there was kind of a
20 joint defendants' motion, and we each peeled off and filed
21 individuals. And the statute of limitations motions we've been
22 talking about I think are in the Mylan and Sandoz individual
23 motions. Is that right?

24 MR. ANGLAND: That's correct.

25 MR. MERKL: And it is basically the same motion, that

1 as of '98 -- I'm sorry -- three years back from 2002 when it
2 was filed in '99, everything before that is barred because
3 California should have been on inquiry notice as to what
4 happened. And they've raised some objections to that based on
5 California law, whether it's enough for the head of DHS, the
6 Department of Health Services, to know or whether the Attorney
7 General has to know, whether this stuff really is good enough
8 notice and --

9 THE COURT: Okay, so that's all that's unique to your
10 two companies?

11 MR. MERKL: We both have that. Then Mylan has the
12 motion on Mylan, Inc. to get out because it's a holding
13 company, and it is not actually the company that sells,
14 markets, and does this stuff.

15 THE COURT: Haven't I ruled on this before?

16 MR. MERKL: I think you did rule on it -- I think you
17 might have resolved it in the past. It's come up before.

18 THE COURT: It sure has. I just, you know, I don't
19 remember --

20 MR. MERKL: I don't remember. Their argument is that
21 because --

22 THE COURT: I don't want to -- if I've done it, could
23 you just find out where I did it. Mylan must know somewhere.

24 MR. MERKL: I think this has come up. I don't think
25 it's come up with Mylan, though.

1 MR. PAUL: Your Honor, we haven't located any, unless
2 it happened since the briefing.

3 MR. MERKL: I'll double-check. It may be we did it
4 and it was resolved, but I don't think you've ruled on it.

5 THE COURT: Didn't this come up in the -- I don't
6 remember.

7 MR. MERKL: It may be, your Honor, in another Mylan
8 case that we've since settled or resolved some of this, and it
9 never had to be decided.

10 THE COURT: Yes, I thought it did. Judge Bowler ruled
11 on it and it came up. Anyway, could you just take another pass
12 through. It's possible that it was another one of the
13 corporations with a similar issue.

14 MR. MERKL: Mylan has another issue that you have
15 ruled on in the past, and there's citations in the papers where
16 we settled an antitrust case involving the claims on two drugs.
17 Our claim basically is, it's transactional, that, you know, you
18 brought a case --

19 THE COURT: Have I rejected that before?

20 MR. MERKL: You ruled against that.

21 THE COURT: All right, so you're just making a
22 placeholder there?

23 MR. MERKL: Yes.

24 THE COURT: Okay, okay. I have too much to do to go
25 back and revisit it, but, okay.

1 MR. MERKL: Well, believe me, it's not a lot of the
2 papers.

3 THE COURT: Okay, all right.

4 MR. ANGLAND: And, your Honor, Sandoz, as counsel just
5 mentioned, had one other Sandoz-specific summary judgment
6 motion. That was based upon the submission of AMPs
7 undercutting the scienter element of a claim under California
8 law.

9 THE COURT: Is this AMPs to the Center for Medicare
10 and Medicaid Services?

11 MR. ANGLAND: Yes, and Sandoz submitted them to
12 California as well, and that was drug by drug --

13 THE COURT: I see. So this was not part of the
14 Medicaid rebate agreement?

15 MR. ANGLAND: It was all -- they were created for the
16 purpose of a Medicaid rebate agreement; but rather than just
17 sending them to the federal government, which I believe is all
18 Sandoz had to do, it actually sent them to the state of
19 California as well, and it lists drug by drug what the actual
20 after-discount transaction price is.

21 THE COURT: That's interesting.

22 MR. ANGLAND: It didn't do that for the entire period,
23 your Honor. It did it through 1997. For the years after 1997,
24 we have the argument that California had the URA and could
25 quickly have computed it. And if I can --

1 THE COURT: Yes, but I've rejected that up and down,
2 but --

3 MR. ANGLAND: Well, if I may, your Honor, there's one
4 paragraph on that --

5 THE COURT: But you're unique because I think most
6 people don't send the AMPs directly to the state, so --

7 MR. ANGLAND: And that's why we made this ourselves.
8 In the Mylan case, you do reject a version of the argument but
9 not the argument that we're making here, your Honor, if I can
10 make the distinction. In the Mylan case, your Honor says,
11 "Well, yes, they might have had the URAs from which AMPs could
12 be computed, but they didn't compute them, and therefore I will
13 not find that this constituted state approval of these big
14 spreads."

15 We are not raising AMPs in that context here. We are
16 saying it goes to Sandoz's scienter, not government approval,
17 but to whether we had bad intent.

18 THE COURT: I would never do that as a matter of law.
19 It may be relevant evidence for a court to take in.

20 MR. ANGLAND: As my last shot on this, your Honor, and
21 it will only take a moment, I would say that analytically what
22 we have here, although not quite as neat, is really not
23 different from a situation wherein California said, "Please
24 send us your published AWP," and we sent them the so-called
25 inflated AWP, but we had a column next to it that said "real

1 price."

2 THE COURT: Did you?

3 MR. ANGLAND: The AMPs were the real price. They were
4 not on the same piece of paper.

5 THE COURT: Well, but the actual AMPs makes an
6 interesting question. That's different than the reverse
7 engineering, the URAs that go to a different agency.

8 MR. ANGLAND: Right, we had actual AMPs through '97,
9 reverse engineering for the next few --

10 THE COURT: And you sent the AMPs directly to the
11 Medicaid agency?

12 MR. ANGLAND: Directly. We have the exhibit there,
13 and it's drug by drug. And if I can add, your Honor --

14 THE COURT: No, no, can I -- yes, go ahead.

15 MR. ANGLAND: When their expert does his report to
16 figure out what his "but for" prices are, they're basically
17 almost identical to our AMPs. I mean, they're extremely close.

18 THE COURT: So what happens there? We actually had
19 that come up in the Mylan case where at some point
20 Schering-Plough actually sent them what the real price was.

21 MR. PAUL: That's different, your Honor. The AMPs are
22 part of California's mandatory supplemental rebate program,
23 which is a way to contain costs; and, as counsel accurately
24 states, Sandoz did for a period report its AMPs to the state,
25 as required to do so, in order to enter into a supplemental

1 rebate contract. But that information -- and the record
2 establishes this, the evidence that we put in via our summary
3 judgment motion -- it's protected just as closely in the rebate
4 shop. This is all rebates. It may be state rebates but it's
5 rebates. It's highly confidential. Every pharmaceutical
6 manufacturer has always insisted on protecting their AMPs and
7 affording them that kind of confidentiality.

8 So, no, no one in the California program took their
9 AMPs and compared them to their AWP's. And we have briefing
10 there additionally, your Honor. The industry seems to have
11 adopted a curious position on the accuracy of AMPs, as we
12 explained to you, regarding the stance taken by the Generic
13 Pharmaceutical Association, of which Sandoz sits on the
14 Executive Committee, coincident with the recent new FUL formula
15 based on AMPs which are now in the open, and they've disavowed
16 the accuracy of AMPs as a basis for reimbursement. So I think
17 that kind of undercuts any assertion that this number was
18 useful to compare.

19 THE COURT: I don't think drug pricing will ever be
20 clear.

21 MR. ANGLAND: There are really two points there.
22 First is, could California have used the AMPs to compare them
23 to the real prices and say, "Whoa, there were spreads here of
24 1,000 percent or 2,000 percent"? Absolutely nothing that they
25 cite in their papers says that California can't do that.

1 Now, they do cite evidence that says California could
2 not have created a reimbursement formula based on AMP; and even
3 assuming that's true, that's not our point. Our point is, all
4 you have to do is compare the two. He adds, "Well, we didn't
5 compare them," not that they couldn't but that they didn't
6 compare them. That may be relevant to other issues in this
7 case, but it's not relevant to scienter.

8 THE COURT: But let me just be clear. I understand
9 your point, and it may well be relevant to scienter; and if I
10 were the trial judge, just as I did in the case in
11 Massachusetts, I would allow it in as evidence of scienter, but
12 that doesn't make it so as a matter of law.

13 MR. ANGLAND: Well, you can see why I'm anxious to get
14 this before the trial judge, your Honor.

15 THE COURT: I'm anxious for you to get it in front of
16 that judge too, so --

17 MR. ANGLAND: And I'll sit down after the next
18 sentence, which is basically, yes, several years after all this
19 happened Sandoz said, "We don't like basing reimbursement on
20 AMPs." It didn't like basing reimbursement on any average.
21 Half the people are going to be below, half above, and there
22 are other technical problems.

23 THE COURT: I understand. Okay, that's useful.
24 What's the last issue? Was there another issue, an individual
25 company issue?

1 MR. ANGLAND: I don't think so, your Honor.

2 THE COURT: No? That's it.

3 MR. MERKL: Your Honor, we have some defendant-specific
4 evidence, but it's not a separate dispute issue.

5 THE COURT: Okay. Okay, thank you.

6 MR. BREEN: Your Honor, can I just make one point on
7 AMPs real quick because we keep throwing it around, but I think
8 the record is real clear on this. Until after 2000 in I think
9 Texas -- and we just tried a case last month in Texas that I
10 tried --

11 THE COURT: How did you do?

12 MR. BREEN: \$170 million verdict where AMPs was at
13 issue.

14 THE COURT: State court, was this this kind of case?

15 MR. BREEN: Yes, your Honor. It was against one of
16 the defendants, one of the co-defendants in the federal case,
17 Actavis.

18 THE COURT: I think every single jury that's tried one
19 of these cases has come back for the plaintiffs, with Alabama,
20 the Supreme Court reversing one verdict, right?

21 MR. BREEN: Exactly, and that was a reasonable
22 reliance case for brands. And AMPs, your Honor, were in that
23 case, and they were in the Texas case only because Texas
24 required them to be reported after 2002 to the reimbursement
25 people. And if your Honor will recall, in the Warrick case,

1 Texas started the Warrick case also with our Ven-A-Care Texas
2 case against Warrick. They began to report AMPs in connection
3 with reimbursement and authorized the states to use them. So
4 until a state actually asked for AMP for reimbursement
5 purposes, or a defendant says, "Here, use it for reimbursement
6 purposes," those are the only instances that I'm aware of where
7 AMP has been relevant to the knowledge of the defendant. Other
8 than that, everybody knows they're being used for rebate
9 purposes and they're not being used for reimbursement purposes.

10 THE COURT: Okay, thank you. Can I see counsel at
11 side bar just for one -- I don't know who's sitting out there.
12 Actually, I know some of the people who are sitting out there,
13 but I'm going to talk the "S" word.

14 (Side-bar conference off the record.)

15 (Adjourned, 11:54 a.m.)
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C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I, Lee A. Marzilli, Official Federal Court Reporter,
do hereby certify that the foregoing transcript, Pages 1
through 51 inclusive, was recorded by me stenographically at
the time and place aforesaid in Civil Action No. 01-12257-PBS,
In Re: Pharmaceutical Industry Average Wholesale Price
Litigation, and thereafter by me reduced to typewriting and is
a true and accurate record of the proceedings.

In witness whereof I have hereunto set my hand this 22nd
day of February, 2011.

/s/ Lee A. Marzilli

LEE A. MARZILLI, CRR
OFFICIAL FEDERAL COURT REPORTER